REMARKS

Claims 1-5 and 7-16 are pending in the application. In the Office action dated April 5, 2004, the examiner rejected all claims under 35 U.S.C. § 103(a) as purportedly being unpatentable over the following combinations of references: US '369 in view of US '332; US '732 in view of US '332; and WO '282 in view of US '332. In each case, the secondary reference, US '332, is cited for its disclosure that "cyclodextrin increase[s] the water solubility of many drugs by complexing them into the hydrophobic cavity of the cyclodextrin..." See, e.g., pages 3, 5, and 6 of the April 2004 Office action. Applicant has carefully studied each of the cited references, and respectfully submits that the examiner's conclusion is unwarranted. There is no bona fide motivation to combine the references' respective teachings and, even if so combined, the references would not yield the presently claimed invention. In addition, Applicant is submitting herewith a declaration under 37 C.F.R. § 1.132, wherein the inventor, Roger D.A. Lipman, Ph.D., provides compelling, objective evidence of a long-felt need for the invention and unexpected results realized by the invention. His declaration readily establishes that the invention is not obvious in view of the cited references.

I. THERE IS NO MOTIVATION TO COMBINE THE '332 PATENT WITH EACH OF THE PRIMARY REFERENCES.

As the examiner acknowledges, obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so, found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In the present case, however, no such motivation exists.

The examiner states that the motivation lies in the teaching of the '332 patent that drugs complexed with cyclodextrin enable steady-state drug release because cyclodextrin increases the water solubility of many drugs. Nothing in any of the primary references, however, indicates a

need for such steady-state drug release, so the skilled person would not look to the '332 patent. US '369, for example, states that "[t]he purpose of incorporating the hydrocolloid in the other components so as to form the gel-like composition is to retain a tight seal both between the shaped sealing material and the stoma, and between the sealing material and the skin..." A person having ordinary skill in the art, reading that passage in the '369 patent, might look for other materials to provide a tight-seal, but would not look to the '332 patent and its disclosure regarding the benefits of cyclodextrin in steady-state drug release. The skilled person would not find motivation in the '332 patent to substitute cyclodextrin for one of the hydrocolloids disclosed in the '369 patent.

The '369 patent also provides two other reasons why the skilled person would not look to the '332 patent and its disclosure of cyclodextrin in a transdermal drug delivery system. The '369 patent, at column 6, lines 24-38, gives examples of "suitable hydrocolloids" but does not list cyclodextrin. As explained in the accompanying Declaration of Roger Lipman, cyclodextrin has been known for many years, since the 19th century. The fact that it is not listed among the hydrocolloids identified in the '369 patent, which issued in 1980, surely implies that it is not suitable for the task disclosed in'369 patent: retaining a tight seal between the sealing material and the stoma, and between sealing material and the skin. Indeed, the '369 patent states that "the best mixture of hydrocolloids for use in the sealing material according to the invention, is a mixture of...sodium carboxymethyl cellulose...[and] guar gum." (Column 7, lines 33-38.) The '369 patent also states that "starch is a hydrocolloid not very suitable for the present purpose." (Column 7, lines 21-22, emphasis added.) Cyclodextrin, however, is derived from starch. Consequently, the skilled person would not find any motivation to replace one of the hydrocolloids disclosed in the '369 patent with cyclodextrin, notwithstanding the '332 patent's unrelated disclosure that cyclodextrin increases the water solubility of many drugs.

There is a similar lack of motivation to combine the teachings of the '732 patent with those of the '332 patent. The '732 patent discloses a skin barrier in which an adhesive material consists of a hydrocolloid dispersed in a continuous phase of, e.g., a crosslinked elastomer,

tackifier, plasticizer, and antioxidant. The preferred hydrocolloid is sodium carboxymethyl cellulose. (See, e.g., the abstract and column 6, lines 50-52.) According to the '732 patent, the purpose of the hydrocolloid "first and foremost is to ensure the adhesion of the skin barrier to skin and mucus membranes even when they are moist." Despite the fact that cyclodextrin was known at the time the '732 patent was filed, it is not listed among the many hydrocolloids described in the '732 patent. A skilled person, reading that the purpose of the hydrocolloid in the '732 patent is to ensure the adhesion of the skin barrier to skin and mucus membranes, would not find in the '332 patent a motivation to select cyclodextrin as the hydrocolloid, notwithstanding the '332 patent's unrelated disclosure that cyclodextrin increases the water solubility of many drugs.

There is also no motivation to combine WO '282 with the '332 patent. Like the other primary references cited, the '282 application lists a number of hydrocolloids, but does not mention cyclodextrin. In the '282 application, the hydrocolloid "functions as the absorbent" and provides the "wet tack that ensures the adhesive adheres to the skin and mucus membranes when they are moist." The skilled person, reading the "282 application and its disclosure that the hydrocolloid is needed as an absorbent and for wet tack purposes, would not be motivated to use cyclodextrin as the hydrocolloid, notwithstanding the unrelated teaching of the '332 patent that cyclodextrin increases the water solubility of many drugs.

Equally important is the fact that, even if one were to combine the teachings of the '332 patent and each of the primary references, the result would not be the presently claimed invention, which requires two hydrocolloids, one of which is cyclodextrin. Without the benefit of the hindsight gleaned from reading the present application, a skilled person, looking at the '332 patent and each of the primary references, would see nothing to suggest that one should use two different hydrocolloids, one of which is a cyclodextrin. At most, the '332 patent identifies a benefit of using cyclodextrin as the hydrocolloid -- in a transdermal drug delivery device where increasing the water solubility of a drug is important. In the '369 patent, however, the hydrocolloid serves a different purpose, and there is nothing to suggest any benefit in including

both a cyclodextrin and a different hydrocolloid to retain a tight seal between sealing material, the stoma, and the skin. Similarly, there is nothing in the '732 patent, even if combined with the '332 patent, to suggest a benefit in using two hydrocolloids, one of which is cyclodextrin, to facilitate adhesion to skin and mucus membranes. Similarly, there is nothing in either the '282 application nor the '332 patent to support the examiner's contention that the skilled person would be motivated to substitute cyclodextrin for one of the hydrocolloids listed in the '282 application.

II. OBJECTIVE EVIDENCE REBUTS ANY CONCLUSION THAT THE PENDING CLAIMS ARE OBVIOUS.

Submitted herewith is the Rule 132 Declaration of Roger D.A. Lipman, Ph.D., the inventor named on the present application. Dr. Lipman has worked continuously with pressure-sensitive adhesives since 1965. He has worked with hydrocolloids for over 25 years. Dr. Lipman convincingly demonstrates that there has been a long-felt need for the present invention, and that the claimed invention achieves unexpected results over the prior art. His declaration is compelling evidence that the pending claims are not obvious. Over the course of his professional career, Dr. Lipman has observed a long-felt need for an improved hydrocolloid-containing PSA, particularly an odor-absorbent PSA. (Lipman Decl., §§ 7-9.) Although hydrocolloid adhesives were invented in 1965, and cyclodextrins have been known since the end of the 19th Century, no one had the vision to combine the two in a PSA until Dr. Lipman succeeded with the present invention.

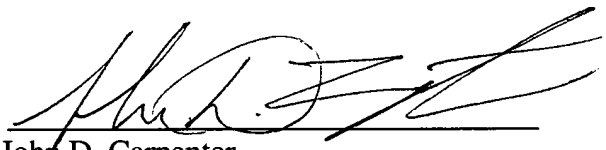
Dr. Lipman also summarizes the striking improvement in odor absorption achieved by the present invention. (Lipman Decl., §§ 10-12.) In the application as filed (pages 30-33, an experiment is described in which hydrocolloid adhesive pads were inoculated with butyric acid, a particularly strong-smelling and offensive compound. The adhesives containing two or more hydrocolloids, at least one of which is a cyclodextrin (Examples 11 and 12) absorbed the butyric acid, and little or no odor was detected by four human panelists. In contrast, the adhesives that contained no cyclodextrin retained the strong odor of butyric acid after 24 hours.

Dr. Lipman describes a second experiment in Paragraph 12 of his declaration, with data presented as Exhibit C. It clearly indicates that a hydrocolloid PSA ("4-108A") containing cyclodextrin and a second hydrocolloid (sodium carboxymethyl cellulose) is a very effective odor absorbent. Water activates the cyclodextrin and greatly enhances the odor-absorbency of the PSA.

Dr. Lipman's declaration is compelling, objective evidence of the nonobviousness of the present invention. Applicant respectfully requests due consideration of this evidence and the arguments presented above. An early notice of allowance is earnestly solicited.

Respectfully submitted,

CHRISTIE, PARKER & HALE, LLP

By 

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